

date of provisional application 60/028,711 (Paper 13, page 2). The Examiner has stated that the amino acid sequence of DR3 (SEQ ID NO: 4 of the '402 patent) has 100 percent identity to SEQ ID NO: 2 of the instant application (AIR polypeptide), and that the amino acid sequence of DR3-V1 (SEQ ID NO: 2 of the '402 patent) has 97.6 percent identity to SEQ ID NO: 2 of the instant application (Paper 13, page 3).

Based on the earliest effective date of the '402 patent as a reference of March 12, 1996, the Examiner has stated that claims 1-3, 6, 7, 10, 11, 13, 14, 16 and 22-26 are anticipated under 35 U.S.C. § 102 (e) by the '402 patent to Yu et al. Applicants traverse this rejection for the following reasons.

Applicants submit herein a Declaration under 37 C.F.R §1.131 to establish that the subject matter of the pending claims was invented in the United States before March 12, 1996. In this Declaration the inventors Dr. Raymond Goodwin and Dr. Mariapia Degli-Esposti declare that they isolated a cDNA encoding the full-length AIR polypeptide (SEQ ID NO: 2 of the present application) before March 12, 1996. This Declaration is supported by Exhibits A and B attached herein.

As described in the instant application, (for example, on pages 18 and 19 of the specification), an analysis of clones derived from a human peripheral blood T cell (hu PBT) library led to the isolation of a full-length cDNA transcript encoding the AIR polypeptide (SEQ ID NO: 2). Page 1 of Exhibit A is a page from a laboratory notebook showing DNA prepared from seven colonies of clone 18.1. Clone 18.1 is the full-length cDNA referred to in the present application, on page 2, lines 31 to 34, and page 19, lines 8 through 18. The upper gel on page 1 shows PCR products generated using oligonucleotide primers showing that all seven colonies of clone 18.1 have inserts. Oligonucleotide primers 18999 and 19000 identified on page 1 of Exhibit A were synthesized based on EST sequences identified in the NCBI EST database as having some homology to human Tumor Necrosis Factor receptor type I, as described on page 18 of the instant patent application. The lower gel on page 1 of Exhibit A shows DNA from clone 18.1 after digestion with EcoRI restriction enzyme.

Page 2 of Exhibit A is a page of a laboratory notebook describing the preparation of DNA from four hu PBT clones 2.1, 17.1, 17.2, and 18.1 for sequencing. Page 3 of Exhibit A shows a picture of a gel of the DNA from clones 2.1, 17.1, 17.2 and 18.1 which was submitted for sequencing. These clones are the clones referred to in the present patent application on page 19, line 8 to 12, as the additional clones isolated from the human peripheral blood T-cell library. All of the activities recorded on these notebook pages were completed in the United States prior to March 12, 1996.

Page 1 of Exhibit B is a copy of the IMMUNEX DNA Sequence Request form showing a request for sequencing DNA prepared from clones 2.1, 17.1, 17.2, and 18.1 isolated from the human PBT library. The DNA was prepared as described in the laboratory notebook pages of Exhibit A. This Request form was completed and submitted prior to March 12, 1996. Page 2 of Exhibit B shows the sequence of the 18.1 clone ("Hu TNFR-like") cDNA which was sequenced and entered into an internal Immunex database in the United States prior to March 12, 1996. The nucleotides encoding the AIR polypeptide are contained within this sequence. SEQ ID NO:1 of the present application, which include the nucleotides encoding the AIR polypeptide of SEQ ID NO:2 of the present application, is indicated by the parenthesis drawn on the sequence.

Therefore, Applicants submit that the enclosed Declaration and accompanying Exhibits A and B establish that the claimed subject matter was invented before March 12, 1996, which is the earliest effective date of U.S. Patent No: 6,153,402 to Yu. et al. as a reference under 35 U.S.C. § 102 (e). In light of the accompanying Declaration and Exhibits, Applicants submit that the rejection of the pending claims on the basis of 35 U.S.C. § 102 (e) has been overcome.

CONCLUSION

In light of the foregoing remarks and the Declaration under 37 C.F.R §1.131 with accompanying Exhibits A and B submitted herein, Applicants respectfully request that the rejection of claims 1-3, 6, 7, 10, 11, 13, 14, 16 and 22-26 under 35 U.S.C. § 102 (e) be

withdrawn, and the claims allowed. Applicants' Attorney requests that the Examiner call her at the number given below if it would assist in the prosecution of this application.

Respectfully submitted,

Christine Bellas

Christine Bellas
Registration No. 34,122
Attorney for the Applicants

Immunex Corporation
51 University Street
Seattle, WA 98101
Telephone (206) 265-6294

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Date:

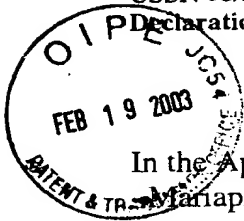
January 21, 2003

Signed:

Kathleen F. Prindle
Kathleen F. Prindle

USSN 08/943,776

Declaration under 37 C.F.R. § 1.131



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Mariapia A. Degli-Esposti and Raymond Goodwin

Docket No.: 2849-A

Serial No: 08/943,776

Examiner: Lazar Wesley, E.

Filed: October 3, 1997

Group Art Unit: 1646

For: NOVEL RECEPTOR THAT CAUSES CELL DEATH

Assistant Commissioner for Patents
Washington DC 20231

DECLARATION UNDER 37 C.F.R § 1.131

Dear Sir:

We, the undersigned, hereby declare that:

1. We are the same Raymond Goodwin and Mariapia A. Degli-Esposti named as co-inventors on the above-identified application serial number 08/943,776. We the co-inventors isolated a cDNA encoding the full-length AIR polypeptide prior to March 12, 1996, as evidenced by Exhibits A and B enclosed herein. All actions, events and observations described in this Declaration were completed in the United States prior to March 12, 1996.

2. Exhibit A includes copies of pages from a laboratory notebook. Page 1 of Exhibit A shows gels of plasmid DNA prepared from seven colonies of clone 18.1 isolated from a human peripheral blood T cell (hu PBT) library. The upper gel shows PCR products generated using oligonucleotide primers 18999 and 19000 to show that all seven colonies have inserts. The lower gel shows DNA prepared from clone 18.1 colonies after digestion with EcoRI restriction enzyme. Page 2 (bottom half) of Exhibit A describes the preparation of DNA from four hu PBT clones 2.1, 17.1, 17.2, and 18.1, which was then submitted for sequencing. Page 3 of Exhibit A shows a gel of the DNA prepared from clones 2.1, 17.1, 17.2, 18.1 submitted for sequencing.

3. Exhibit B page 1 is a copy of an IMMUNEX DNA Sequence Request form showing a request for sequencing the cDNAs prepared from clones 2.1, 17.1, 17.2, 18.1 as described above. This Request Form was submitted prior to March 12, 1996. Exhibit B page 2 shows the sequence of the 18.1 clone ("Hu TNFR-like") cDNA which was sequenced and entered into an internal Immunex database prior to March 12, 1996. The nucleotides identical to SEQ ID NO: 1 of the present application, which are the nucleotides encoding the AIR polypeptide (SEQ ID NO:2), are contained within this sequence, and are indicated by the parenthesis drawn on the sequence.

4. Clones 2.1, 17.1, 17.2, and 18.1 referred to in paragraphs 2 and 3 above are the clones described on page 19, lines 8 through 11 of the present application. The sequence of the insert in clone 18.1 contains the cDNA encoding the AIR polypeptide (SEQ ID NO: 2) as described in the present application on page 2, lines 32 to 37, page 19, lines 15 to 18, and as shown in SEQ ID NO: 1. The portion of this sequence identical to SEQ ID NO: 1 is contained within the parenthesis indicated on this sequence.

5. Exhibits A and B are sufficient to show that cDNA clone 18.1 encoding the AIR polypeptide of SEQ ID NO: 2 had been isolated before March 12, 1996. The work recorded in the laboratory notebook pages in Exhibit A and the sequencing work shown in Exhibit B were completed in the United States prior to March 12, 1996.

6. We further declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like

USSN 08/943,776
Declaration under 37 C.F.R. § 1.131

so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date <u>1/21/03</u>	<u>Raymond C. Goodwin</u> Raymond Goodwin
Date <u>15 January 2003</u>	<u>Mariapia Degli-Esposti</u> Mariapia A. Degli-Esposti

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date shown below.

Date: <u>January 21, 2003</u>	Signed: <u>Kathleen F. Prindle</u> Kathleen F. Prindle
-------------------------------	---

TITLE Human pB1 DNA 18-1 cnpBlue script subclones

From Page No. _____

Hu PB1 18-1 clone in pBS - DNA was prepared from 7 colonies
needs to be checked for presence of insert

PCR with EST specific primers 18999 and 19000

Template - 2µl DNA

PCR MIX

10x PCR buffer #7	50µl	94°C	5min	} 30 cycles
25mM dNTPs	4µl	94°C	45"	
10µM 18999	50µl	55°C	45"	
10µM 19000	50µl	72°C	1min	
AmpliTaq	5µl	72°C	5min	
ddH2O	34µl			

1. Hu PB1 18-1 pBS # 22
2. 23
3. 24
4. 25
5. 26
6. 27
7. 28

8. ddH2O

9. 769 2-1-1a L1 colony pick

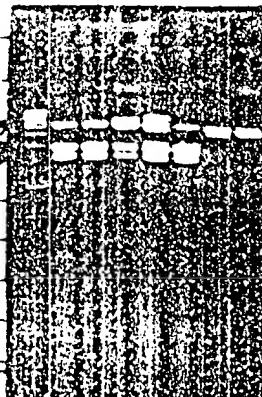
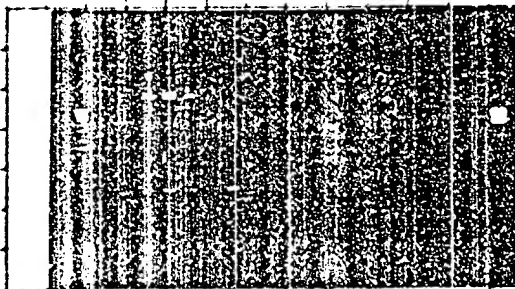
10. 5.1 For Brain λ DNA 2µl of 25ng/µl

Result of PCR shows all seven colonies have inserts

18-1 DNA was also digested with EcoRI

10x buffer H	20µl
1mg/ml BSA	2µl
EcoRI 20u/ml	10µl
ddH2O	118µl

↳ 45µl + 5µl DNA 37°C 2hrs → add 2µl 0.5M EDTA ←



Digest checked

Result:

Perk Pto # 22-26 cut
#27-28 uncut
#22 was probed
for sequencing

To Page No. _____

⑥ 789 subclones amplified with PBS primers

PCR products 2-1-1a L3

Engle

40µl 2-1-1b L9

Engle

2-1-2b L11 were dir. prep'd and quantitated
resuspended in 20µl

⑦ PEG purify HU PBT DNA prepared by the mini prep method on

2-1, 13-1; 13-2; 13-1

submit
for
sequencing

DNA in PCR II # 2 a and b → for Riboprobe prep see ①

see photo next page

⑧ Prepare DNA and PEG purify from 789 subclones 2-1-1a L3

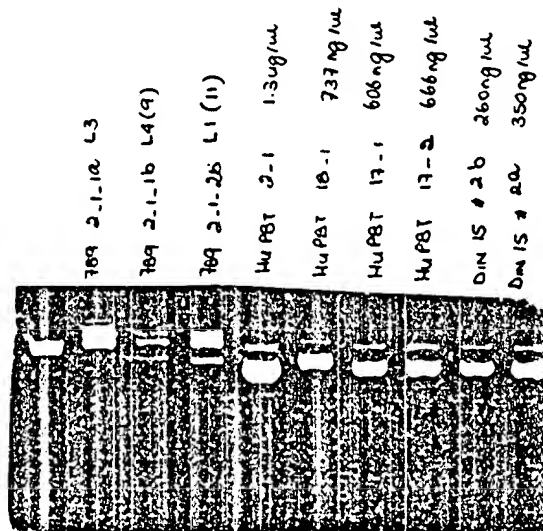
submit for sequencing

2-1-1b L9 (4)

2-1-2b L11 (1)

To Page No. _____

picture of DNA submitted for sequencing



RG

DNA SEQUENCE REQUEST FORM

RESEARCHER:

attach photo here

PROJECT NAME: *EST*
(to charge time to)

NAME OF CLONE: *2.1, 18.1, 17.1, 17.2*

(Include VAX/GCG file name or attach seq)

Plasmid DNA: 1ul ea sample
also 1ul 1:5 dil. if > 1mg/ul
w. 200ng Lambda-H3
1% agarose / TAE gel
PCR fragment: 5ul of sample
w. 200ng PhiX-Hae3
1.5% agarose / TAE gel
ethidium stain after running

PREP. METHOD: (Immunoprep, Maxi, Qiagen, Magic, Wizard, PCR, Other)
If OTHER, please specify: *Resin*

Has this preparation been PEGed?

YES

NO

Has it, or a related molecule, been sequenced at IMMUNEX previously? *Yes*

SEQ REQ# _____ SEQUENCER *Marty + Jennette*
(HUTNER like Est)

COMMENTS: (Pertinent Information, amount of sequence needed, available oligos, PCR amplification primers, insert size etc.)

2.1 ~ 1.6 kb
18.1 ~ 3 kb
17.1 ~ 1.4 kb
insert 17.2 ~ 1.4 kb bases

vector

cloning site

cloning site

Human PBT cDNAs in
EcoRI site of pBluescript

Clones 17.1, 17.2 also use internal primers

2.1, 18.1 = # 19585
19588

17.1, 17.2 # 19588, 19575

1

Request#: *3631*

1

Sequencer: *J. Bertles*

HuTNFR-like

USSN 08/943,776

Declaration Under 37 C.R.F. 1.131

Exhibit B

Page 2 of 2

HuTNFR-like Length: 2696

1	TACGCCAAGC	TCGAAATTAA	CCCTCACTAA	AGGGAACAAA	AGCTGGAGCT
51	CCACCGCGGT	GGCGGCCGCT	CTAGAACTAG	TGGATCCCCC	GGGCTGCAGG
101	AATTCCGGTT	TTTTTTCTTT	TTTTTGCACA	ATAAAAAGTC	TTTCCATTAG
151	AAACACAAAG	ACGTGAGAGG	AAGGGTTTGC	ATTAATGGGC	TTGGGTTTTTC
201	CACAATTTTG	AATTAATAAC	CTATAGCACC	TCCCAGCACA	GAACAATTCA
251	TTTCATTATT	TTTAATAAAC	CCAATTTACA	GCAAACCTTAC	GGAAGTTCTC
301	GGATTTTTCAG	TGAAATATGT	ATTAGGTTGG	TGCAAAAGTA	ATTGCAATTT
351	TTGCAATTAC	TTTCCATGGT	AAAAAAAAAT	GCAATTACTT	TTGCACAAAC
401	TTAAATAGGT	TTCATTCACT	CTTTAGATCT	CAGCCATTTG	GGATGAGATT
451	CAGAACCAAA	CACTGAGAAG	CAGAGGCCAG	GGGAAGGAGA	GGTCCGTGGC
501	TCTGAAAGAT	ACTGCAGACA	CGAAGCCCAG	GACGTGAAGA	AGTGCCTCCC
551	GAGCATGTTT	CCGCTCCGCG	TGCACATCCA	GCTCACACAC	TTGTCGTGGC
601	CGGTACTGAT	CACCCACTCT	GTGGCCAAGC	TGAAGATAAT	CGCAGACACC
651	CGGTTCTGAT	GAGCTGGGTA	GGTCTTGATA	AAGTTCATTT	TATTAAATC
701	TTCAGAAACG	TGAAATTCCA	TTACAGCTCC	ATTATCCTGG	CCCACAAATA
751	TCCGTCTGCT	GTCATGATGG	TAAGCCATAG	CAGAGCAAGG	AGAGGCCATT
801	GTGTGGTAAA	TGCTGGGCCA	GTATTGACCA	CTGTCTCTTT	TCAGCCATAC
851	CCGGATGGTT	CTGTCTCTCG	TGGCCGTGAT	CACGCCGTCC	TCCTTGGGGA
901	TGAGCAGCGC	GGCCGTGACG	GCGTCCTGGT	GCCCCCTCGAT	CTTGCTCAGC
951	AGCACCGGGC	GGCTGCTCTG	CGGCCTGGAG	TGGATTTTCGG	CCGCCATGTT
1001	CGCGCGGCGA	CTGCTGCGGC	CTCCTCGGCA	GGCAGCCCAT	CAGCTGACGC
1051	CTGGGCGCCC	GTCGGAGGGC	TATGGAGCAG	CGGCCGCGGG	GCTGCGCGGC
1101	GGTGGCGGCG	GCGCTCCTCC	TGGTGCTGCT	GGGGGCCCGG	GCCCAGGGCG
1151	GCACTCGTAG	CCCCAGGTGT	GACTGTGCCG	GTGACTTCCA	CAAGAAGATT
1201	GGTCTGTTTT	GTTGCAGAGG	CTGCCCAGCG	GGGCACTACC	TGAAGGCCCC
1251	TTGCACGGAG	CCCTGCGGCA	ACTCCACCTG	CCTTGTGTGT	CCCCAAGACA
1301	CCTTCTTGGC	CTGGGAGAAC	CACCATAATT	CTGAATGTGC	CCGCTGCCAG
1351	GCCTGTGATG	AGCAGGCCTC	CCAGGTGGCG	CTGGAGAACT	GTTCAGCAGT
1401	GGCCGACACC	CGCTGTGGCT	GTAAGCCAGG	CTGGTTTGTG	GAGTGCCAGG
1451	TCAGCCAATG	TGTCAGCAGT	TCACCCTTCT	ACTGCCAACC	ATGCCTAGAC
1501	TGCGGGGCCC	TGCACCGCCA	CACACGGCTA	CTCTGTTCCC	GCAGAGATAC
1551	TGACTGTGGG	ACCTGCCTGC	CTGGCTTCTA	TGAACATGGC	GATGGCTGCG
1601	TGTCCTGCCC	CACGAGCACC	CTGGGGAGCT	GTCCAGAGCG	CTGTGCCGCT
1651	GTCTGTGGCT	GGAGGCAGAT	GTTCTGGGTC	CAGGTGCTCC	TGGCTGGCCT
1701	TGTGGTCCCC	CTCCTGCTTG	GGGCCACCCT	GACCTACACA	TACCGCCACT
1751	GCTGGCCTCA	CAAGCCCCTG	GTTACTGCAG	ATGAAGCTGG	GATGGAGGCT
1801	CTGACCCAC	CACCGGCCAC	CCATCTGTCA	CCCTTGGACA	GCGCCACAC
1851	CCTTCTAGCA	CCTCCTGACA	GCAGTGAGAA	GATCTGCACC	GTCCAGTTGG
1901	TGGGTAACAG	CTGGACCCCT	GGCTACCCCG	AGACCCAGGA	GGCGCTCTGC
1951	CCGCAGGTGA	CATGGTCTCT	GGACCAGTTG	CCCAGCAGAG	CTCTTGCCCC
2001	CGCTGCTGCG	CCCACACTCT	CGCCAGAGTC	CCCAGCCGGC	TCGCCAGCCA
2051	TGATGCTGCA	GCCGGGCCCG	CAGCTCTACG	ACGTGATGGA	CGCGGTCCCA
2101	GCGCGGCGCT	GGAAGGAGTT	CGTGCGCACG	CTGGGGCTGC	GCGAGGCAGA
2151	GATCGAAGCC	GTGGAGGTGG	AGATCGGCCG	CTCCGAGAC	CAGCAGTACG
2201	AGATGCTCAA	GCGCTGGCGC	CAGCAGCAGC	CCGCGGGCCT	CGGAGCCGTT
2251	TACGCGGCC	TGGAGCGCAT	GGGGCTGGAC	GGCTGCGTGG	AAGACTTGCG
2301	CAGCCGCCTG	CAGCGCGGCC	CGTGACACGG	CGCCCCTTG	CCACCTAGGC
2351	GCTCTGGTGG	CCCTTGACAG	AGCCCTAAGT	ACGGTTACTT	ATGCGTGTAG
2401	ACATTTTATG	TCACTTATTA	AGCCGCTGGC	ACGGCCCTGC	GTAGCAGCAC
2451	CAGCCGGCCC	CACCCCTGCT	CGCCCTATC	GCTCCAGCCA	AGGCGAAGAA
2501	GCACGAACGA	ATGTCGAGAG	GGGGTGAAGA	CATTTCTCAA	CTTCTCGGCC
2551	GGAGTTTGGC	TGAGATCGCG	GTATTAAATC	TGTGAAAGAA	AACAAAAAAA
2601	AAAAAACCGG	AATTGATAT	CAAGCTTATC	GATACCGTCG	ACCTCGAGGG
2651	GGGGCCCGGT	ACCCAATTCG	CCCTATAGTG	AGTGTATTA	